



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 16, 2016

David L. Anderson
Regulatory Affairs, Director
Rainbow Treecare Scientific Advancements
11571 K-Tel Drive
Minnetonka, MN 55343

Subject: Label Amendment – Adding “me-too” use on palms
Product Name: Bacastat 4.3
EPA Registration Number: 74779-16
Application Date: March 03, 2016
Decision Number: 515228

Dear Mr. Anderson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Fatima Sow by phone at (703) 347-8308, or via email at sow.fatima@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'HJ', written in a cursive style.

Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Bacastat™ 4.3

Bacastat™ 4.3 is an injectable systemic antibiotic for the control of certain bacterial diseases in non-food bearing ornamental trees.

Active Ingredient	
Oxytetracycline Hydrochloride*.....	4.3%
Other Ingredients.....	<u>95.7%</u>
Total	100.00%

*Equivalent to 3.94% oxytetracycline
Contains 0.38 pounds of oxytetracycline hydrochloride per gallon

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See Side/Back Panel for Additional Precautionary Statements, First Aid and Directions for Use

EPA Reg. No. 74779-16

EPA Est. No. XXXXX-XXX

Net Contents:

Rainbow Treecare Scientific Advancements

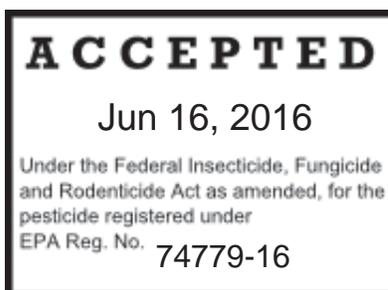
11571 K-Tel Drive

Minnetonka, MN 55343

1-877-ARBORIST

1-877-272-6747

www.treecarescience.com



FIRST AID:	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
IF ON SKIN	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 – 20 minutes • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
For 24 hour medical emergency assistance (human or animal), or chemical emergency assistance (spill, leak or accident). Call CHEMTREC at 1800-424-9300	
NOTE TO PHYSICIAN: There is no specific antidote available. Treat patient symptomatically.	

**PRECAUTIONARY STATEMENT
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Avoid contact with skin, eyes or clothing. Causes moderate eye irritation. Wear protective eyewear such as goggles or shielded safety glasses. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Personal Protective Equipment (PPE)

Some materials that are chemical resistant to this product are listed below. Applicators and other handlers must wear:

- Long sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves (polyethylene or butyl rubber or neoprene rubber or Viton).
- Protective eyewear (goggles, face shield or safety glasses).

User Safety Requirements:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Immediately remove clothing/PPE if pesticide gets inside; then thoroughly wash and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, thoroughly wash and change into clean clothing.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Physical or Chemical Hazards

Do not mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

This product contains the antibiotic oxytetracycline. To reduce the development of drug-resistant bacteria and maintain the effectiveness of this and other antibacterial products, this product should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Restrictions:

- This material is not to be used for medical or veterinary purposes.
- Do not apply this product through any type of irrigation system.
- To be used on non-crop bearing ornamentals only. This product is not to be used on trees that will produce food (nuts, fruit, or sap) within the year following treatment.
- Do not inject trees that are less than two inches in diameter.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box apply to uses that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:

- Coveralls over long-sleeved shirts and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

Product Information

Bacastat 4.3 is a ready-to-use antibiotic for use on non-crop bearing ornamental trees, palms and large woody shrubs to provide seasonal suppression of mycoplasmas, xylem-limited bacteria, yellows diseases and certain bacterial blight diseases. Bacastat 4.3 is designed for use with Rainbow Treecare tree injection devices. It may be used with other injection devices that meet the label and dose requirements. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height ("DBH"). DBH is the outside bark diameter of the trunk at 4.5 feet (1.37m) above the ground. The diameter is determined by measuring the circumference of the tree at DBH, and dividing circumference (in inches) by three (3). To determine DBH for multi-stemmed woody ornamentals, measure the DBH for each stem or branch and add together for the total DBH per tree.

Application in Ornamental Trees and Shrubs

For Treatment of Bacterial Leaf Scorch, Fire Blight, and Ash and Elm Yellows.

Apply once per growing season. For optimum distribution and uptake, apply when leaves are $\frac{3}{4}$ to full development. For Bacterial Leaf Scorch make treatments in the spring or early summer prior to disease symptoms. For Fireblight, apply prior to petal fall. Treatment will suppress symptoms only in the year of treatment. Re-treatment is required each growing season for continued suppression of symptoms. Using this product in combination with sound cultural treatments such as mulching, irrigation during periods of drought, and management of insect and disease pests is helpful in suppressing symptoms and delaying the onset of decline.

Dosage Rate:

Micro-Injection (Small volume devices)

Inject 3 mls per DBH inch.

Macro-Injection (Large Volume System):

Bacastat 4.3 may be diluted with water to enable use with macro-injection systems. For most macro-injection equipment, dilute with 10 to 150 ml of water per 3mls of Bacastat 4.3 to enable uniform distribution. Note: use diluted product as soon as possible.

Tank Mix: When tank mixing Bacastat 4.3 with other materials, conduct a compatibility test (jar test) using relative proportions of tank mix ingredients prior to mixing ingredients in application equipment. When tank mixing this product with other pesticides observe the more restrictive label limitations and precautions. No label dosage rates may be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing.

Placement of Application/Injection Sites: Inject within 12" of the soil at the base of the tree into the root flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay.

Number of Injection Sites: For optimum results, calculate the number of injection sites by dividing the DBH in inches by 2.

Example: For a tree with a DBH of 16 inches (or circumference of 48 inches):

- 1) DBH = 16 inches (Circumference 48" ÷ 3 = 16")
- 2) Divide DBH of 16 inches by 2 = 8 injection sites
- 3) Dosage Rate = Micro Injection: 48 mls (DBH 16" x 3 mls/inch)
Macro Injection (3 ml Bacastat/10 mls of water): 48 mls + 160 mls water for total of 208 mls of solution to be injected.

Table 1: Example dosage rates

Circumference (Inches)	DBH (Inches)	Number of Injection sites	Dosage mls (Micro injection)	Dosage mls (Macro Injection) (10 mls water per DBH Inch)
24	8	4	24	24 + 80 mls water (104 mls of solution)
36	12	6	36	36 + 120 mls water (156 mls of solution)
48	16	8	48	48 + 160 mls water (208 mls of solution)
60	20	10	60	60 + 200 mls water (260 mls of solution)

Work around the tree, spacing injection sites approximately every 6 inches of tree's circumference or according to the manufacturer's recommendation for the application device.

Drill Depth: Drill through the bark then 1" (hardwoods) or 1 1/2" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Precautions should be taken to avoid areas with decay.

Application in Palms

For Treatment of Lethal Palm Yellows and Texas Phoenix Palm Decline

Apply every 3 months for protection from disease. For suppression of symptoms in a symptomatic palm use up to 3 times the dosage rates below. Once symptoms subside return to a preventative dosing schedule.

Table 2: Preventative Concentrate Dosage Rate:

Small Palm	Average Palm	Large Palm
< 6' Clear Trunk	6' – 15' Clear Trunk	> 15' Clear Trunk
15 mls	24 mls	33 mls

Placement of Injection Site: Inject into the trunk within 2 – 3 feet of the soil.

Drill Depth: Drill to a depth of 4 inches. Use clean, sharp drill bits.

Number of Injection sites: Due to the nature of the Palm's vascular system only one injection site is needed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool place over 45° F with units in an upright position. Do not expose material to temperatures in excess of 85° F for prolonged periods.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

Notice: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Tree injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or tree conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS or seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS and seller harmless for any claims relating to such factors.

RAINBOW TREECARE SCIENTIFIC ADVANCEMENTS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions. This warranty does not extend to the use of the product contrary to label instructions, and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, RAINBOW TREECARE MAKES NO WARRANTIES OR MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

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OPTIONAL MARKETING CLAIMS

Ready-to-use

Liquid formulation

Easy [Simple] to use
[Drill,] inject & protect

Systemic

No mixing required

Stable [formulation]

Aids in the [suppression] [control] of fungal and bacterial pathogens systemically

For seasonal suppression [control] of certain diseases of ornamental trees

Suppresses [controls] certain diseases of ornamental trees

Contents [500 ml] [1000 mls] will treat up to [166] [333] trunk diameter inches (DBH).

Bacastat 4.3 can be used on non-crop bearing ornamental trees to treat the following bacterial diseases:

Ash Yellows

Ash

Bacterial blast

Apple

Pear

Bacterial Blight

Flowering Crabapple

Hawthorn

Lilac

Walnut

Bacterial Canker

Hickory

Horsechestnut

Maple

Mimosa

Oak

Persian Walnut

Walnut

Bacterial Leaf Scorch

Elm

Gum

Oak

Oleander

Sycamore

Blossom Blast

Citrus

Grapefruit

Lime

Tea rose

Walnut

Blossom Blight and Canker

Almond

Apricot

Cherry

Peach

Pear

Plum

Bunch Disease

Butternut

Pecan

Walnut

Crown Gall

Flowering Quince

Quince

Decline

Peach

Pear

Nectarine

Fire Blight

Apple

Apricot

Cherry

Chokecherry

Cliff rose

Cotoneaster

Crabapple

Creambush

Firethorn

Flowering Quince

Hawthorn

Indian Hawthorn

Loquat

Mountain Ash

Ninebark

Pear

Pearlbush

Photinia

Plum

Quince

Rose

Serviceberry

Fruit Spot

Avocado

Leaf and Shoot Blight

Mock Orange

Leaf Blight and Brown Rot

Mandarin Orange

Leaf Spot

Basswood

Hibiscus

Magnolia

Lethal Decline

Basswood

Hibiscus

Magnolia

Phloem Necrosis

Elm

Stem Canker

Poplar

Stubborn Disease

Citrus

Tip Dieback

Maple

Vascular Yellows

Ash

Elm

Wetwood / Slime Flux

Apple

Cherry

Elm

Hickory

Maple

Oak

Peach

Pear

Plum

Poplar

Walnut

Witches' Broom (caused by mycoplasma-like organisms)

Apple

Ash

Dogwood

Elm

Lilac

Locust

Peach

Sassafras

X-Disease

Cherry

Chokecherry

Nectarine

Peach

Plum